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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,806	02/29/2000	William James Cook	381552000200	1012

25225 7590 03/25/2003

MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/515,806

Applicant(s)

COOK ET AL.

Examiner

Delia M. Ramirez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,20-22,27 and 29-39 is/are pending in the application.
- 4a) Of the above claim(s) 20,21,27,29 and 30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-4,38 and 39 is/are allowed.
- 6) ☐ Claim(s) 1, 5-12,22,31-32,34-37 is/are rejected. *claim 6?*
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Application

Claims 1-12, 20-22, 27, 29-39 are pending.

Applicant's amendments to the specification, amendment of claims 1, 3-5, 7, 12, 22, addition of claims 31-39, cancellation of claims 13-19, 23-26 and 28, and a new sequence listing in Paper No. 20, filed on 1/13/2003 is acknowledged.

It is noted that while in page 6 of the response filed on 1/13/2003, Applicants request cancellation of claims 13-19, 23-26 and 28, Applicants assert in page 10, lines 1-2 of the response, that claims 6, 13-21, 23-30 have been deleted and that claims 1, 5, 7-12, 20-22, 27 and 29-39 are pending. In view of the conflicting statements in page 10 lines 1-2 of the response, only claims 13-19, 23-26 and 28 have been cancelled as requested in page 6. As such, claims 1-12, 20-22, 27, 29-39 are still pending. Applicants are requested to clarify this issue in response to this Office Action.

As indicated in previous Office Action Paper No. 18, mailed on 7/12/2002, claims 20-21, 27, 29-30 were withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to an invention non-elected without traverse in Paper No. 11, filed 10/4/2001. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

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Inventorship

1. In view of the papers filed on 2/10/2003, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by addition of inventors: Helga Rubsamen-Waigmann and Frank Spaltmann.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Drawings

2. The formal drawings submitted on 1/13/2003 have been reviewed and are approved by a draftsman under 37 CFR 1.84 or 1.152.

Claim Objections

3. Claim 22 is objected to because of the following informalities: the term "a nucleic acid molecule of any one of claims" should be replaced with "the nucleic acid molecule of any one of claims" since the nucleic acid molecule has been defined in each of the claims recited.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5, 6 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 5 is indefinite in the recitation of "complement thereof" as it is unclear which complements are encompassed by the claim. Fragments of any size which are complementary to the polynucleotides claimed can be considered as "complements". Applicants have not defined the term "complement", as it relates to size, in the specification either. If Applicants wish to claim the entire complement, it is suggested that the term "complement" be replaced with "complete complement". Correction is required.
7. Claim 5 is indefinite in the recitation of "nucleic acid comprising a fragment of at least 3500 nucleotides which encodes a polypeptide comprising a fragment of the amino acid sequence of SEQ ID NO: 2" for the following reasons. As written, it is unclear as to which is the polynucleotide from which the 3500 nucleotides are obtained. Furthermore, it is unclear if the term "which" refers to the nucleic acid molecule or the 3500 nucleotides. For examination purposes, it will be assumed that the claim recites "nucleic acid comprising a fragment of at least 3500 nucleotides of a nucleic acid which encodes a polypeptide comprising a fragment of the polypeptide of SEQ ID NO: 2". Correction is required.
8. Claim 6 was rejected due to the recitation of "molecule hybridizes to a nucleic acid molecule...under stringent conditions". Since Applicants have not pointed out disagreements with the Examiner's contentions, this rejection is maintained for the reasons of record.

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9. Claim 22 is indefinite in the recitation of "molecule of any one of claims 1, 2, 3, 4, or 5 to a compound" as it is unclear what the meaning of the term is within the context of the claim. It is suggested that the term be deleted. In regard to the recitation of "65 C, to a compound", it is suggested that for clarity, the term "compound" be replaced with "nucleic acid". Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1, 4-12, 22, 31-32, 34-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1, 4-12, 22, 31-32, 34-37 are drawn in part to (1) a nucleic acid comprising nucleotides 63-4991 of SEQ ID NO: 1, (2) variants of a nucleic acid comprising nucleotides 63-4991 of SEQ ID NO: 1, (3) vectors comprising (1) or (2), (4) host cells comprising (1) or (2), or (5) a method of producing polypeptides encoded by the nucleic acids of (1) or (2). While the specification discloses the polynucleotide of SEQ ID NO: 1 and the polypeptide of SEQ ID NO: 2, the Examiner has been unable to locate support in the specification, as originally filed, for polynucleotides comprising specifically nucleotides 63-4991 of SEQ ID NO: 1 or variants thereof as encompassed by the claims. Thus, there is no indication that nucleic acids comprising

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nucleotides 63-4991 of SEQ ID NO: 1, variants of such nucleic acids as recited in the claims, vectors and host cells comprising said nucleic acids, and methods of producing the polypeptides of nucleic acids comprising nucleotides 63-4991 of SEQ ID NO: 1, were within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in response to this Office Action.

12. Claims 5-12, 22 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

13. This rejection was discussed at length in Paper No. 18, mailed on 7/12/2002 and it is applied to newly added claim 31 for the reasons of record.

14. Applicants assert that claim 6 has been deleted. Applicants argue that the claims 4 and 5 have been now amended to recite variants that have kinase activity or homologs and fragments of SEQ ID NO: 1 which have kinase activity. Applicants further assert that the specification describes the claimed invention as evidenced by Figure 2 and Figure 7. In addition, Applicants argue that a paper by Bork (1998) submitted with the response, does not stand for the unilateral proposition that protein function cannot be predicted using nucleic acid sequence analysis. Applicants argue that they have performed the multi-database analysis advocated by Bork (1998) as shown in Figure 7. In regard to Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995), Applicants argue that the similarities and binding sites referred to in Van de Loo et al. are not an issue in this case, the claims have been amended to recite specific homologs and variants

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with kinase activity, and that the molecules being claimed have greater homology than the 67% homology of the desaturase and hydroxylase disclose in Van de Loo et al. In regard to Broun et al. (Science 282:1315-1317, 1998), Applicants argue that the alterations taught in this reference are not descriptive of alterations in general since one of skill in the art would appreciate that only non-conserved regions must be altered to retain kinase activity.

15. It is noted that while Applicants assert that claim 6 has been deleted, as explained above, due to the conflicting statements in page 6 and page 10 lines 1-2 of the response, claim 6 has not been cancelled. As such, this rejection as it applies to claim 6 is maintained for the reasons of record.

16. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection as it applies to claims 5, 7-12, 22 and 31. The Examiner acknowledges that the claims have been amended to recite specific variants or homologs with kinase activity. However, claims 5, 7-8, 22 are now directed to (1) a nucleic acid comprising a fragment of at least 3500 nucleotides of a nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1 or nucleotides 63-4991 of SEQ ID NO: 1, or (2) a nucleic acid comprising a fragment of at least 3500 nucleotides of a nucleic acid which encodes a polypeptide comprising a fragment of the amino acid sequence of SEQ ID NO: 2. Claims 9-12 and 31 are drawn to vectors and host cells comprising said nucleic acids as well as to a method of producing the polypeptide encoded by such nucleic acids. See claim interpretation above as discussed in claim rejections under 35 USC 112, second paragraph. It is noted that claim 5 recites "nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1 or nucleotides 63-4991 of SEQ ID NO: 1" and "polypeptide comprising a fragment of the amino acid sequence of SEQ ID NO: 2" As such, the

fragment of at least 3500 nucleotides recited in the claim (1) does not have to be a fragment of the polynucleotide of SEQ ID NO: 1 or a fragment of nucleotides 63-4991 of SEQ ID NO: 1, (2) does not have to encode a fragment of the polypeptide of SEQ ID NO: 2. It can be (1) any fragment of at least 3500 nucleotides (any function) of any part of a polynucleotide which comprises SEQ ID NO: 1 or nucleotides 63-4991 of SEQ ID NO: 1, (2) any fragment of at least 3500 nucleotides (any function) of any part of a polynucleotide which encodes a polypeptide comprising a fragment of the polypeptide of SEQ ID NO: 2. While the specification has disclosed the polynucleotide of SEQ ID NO: 1 and the polypeptide of SEQ ID NO: 2 as well as its function, there is no disclosure of the structure or function of (1) a 3500 nucleotide fragment of a nucleic acid comprising the polynucleotide of SEQ ID NO: 1 or nucleotides 63-4991 of SEQ ID NO: 1, (2) a 3500 nucleotide fragment of a nucleic acid which encodes a polypeptide comprising a fragment of the polypeptide of SEQ ID NO: 2. While claim 5 recites that the nucleic acid claimed encodes a polypeptide of kinase activity, the structural limitation recited in regard to the fragment may be completely unrelated to this activity. Therefore, one cannot reasonably conclude that the claimed invention is adequately described.

17. Claims 5-12, 22 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid (1) consisting of at least 3500 nucleotides of the polynucleotide of SEQ ID NO: 1, (2) consisting of at least 3500 nucleotides of nucleotides 63-4991 of SEQ ID NO: 1, or (3) comprising a fragment of the polynucleotide of SEQ ID NO: 1 wherein said fragment encodes a polypeptide having kinase activity, does not reasonably provide enablement for a nucleic acid comprising a fragment of at least 3500

nucleotides of a nucleic acid comprising (1) the polynucleotide of SEQ ID NO: 1 or (2) nucleotides 63-4991 of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

18. This rejection was discussed at length in Paper No. 18, mailed on 7/12/2002 and it is applied to newly added claim 31 for the reasons of record.

19. Applicants assert that claim 6 has been deleted. Applicants argue that the specification provides guidance as to which amino acids are conserved and that Figure 7 shows how the structure is related to kinase function. Furthermore, Applicants assert that only routine experimentation is required to determine which of the variants encompassed by the claims would lose activity. Applicants submit a copy of the *Ex part Mark*, 12 USPQ2d 1904 decision by the Board to further support the argument that no undue experimentation is required to practice the claimed invention.

20. It is noted that while Applicants assert that claim 6 has been deleted, as explained above, due to the conflicting statements in page 6 and page 10 lines 1-2 of the response, claim 6 has not been cancelled. As such, this rejection as it applies to claim 6 is maintained for the reasons of record.

21. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection as it applies to claims 5, 7-12, 2 and 31. The Examiner acknowledges the submission of the *Ex part Mark*, 12 USPQ2d 1904 decision and agrees with the idea that testing a small number of molecules for activity does not constitute undue experimentation. However the scope of claims 5, 7-8, 22 now encompasses nucleic acids comprising a fragment of at least

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3500 nucleotides of (1) a nucleic acid comprising the polynucleotide of SEQ ID NO: 1, (2) a nucleic acid comprising nucleotides 63-4991 of SEQ ID NO: 1, (3) a nucleic acid encoding a polypeptide comprising a fragment of SEQ ID NO: 2. As indicated above, the fragment of at least 3500 nucleotides recited in the claim does not have to be a fragment of the polynucleotide of SEQ ID NO: 1, a fragment of nucleotides 63-4991 of SEQ ID NO: 1, or a fragment of a polynucleotide encoding the polypeptide of SEQ ID NO: 2. It can be any fragment of at least 3500 nucleotides (any function) of any part of a polynucleotide which (1) comprises SEQ ID NO: 1, (2) comprises nucleotides 63-4991 of SEQ ID NO: 1, (3) encodes a polypeptide comprising a fragment of the polypeptide of SEQ ID NO: 2. While the specification has disclosed the polynucleotide of SEQ ID NO: 1 and the polypeptide of SEQ ID NO: 2 as well as its function, there is no disclosure of the structure or function of any fragment of at least 3500 nucleotides as encompassed by the claims. Therefore, one cannot reasonably conclude that the specification is enabling for the full scope of the claims as written.

Claim Rejections - 35 USC § 102

22. Claims 4-12 and 22 were rejected under 35 U.S.C. 102(a) as being anticipated by Berlanga et al. (cited in the IDS) and Duesterhoeft et al. (cited in the IDS).
23. This rejection was discussed at length in Paper No. 18, mailed on 7/12/2002.
24. Applicants assert that claim 6 has been deleted and that the claims have been amended such that they do not encompass the subject matter of the cited references.
25. It is noted that while Applicants assert that claim 6 has been deleted, as explained above, due to the conflicting statements in page 6 and page 10 lines 1-2 of the response, claim 6 has not

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been cancelled. As such, this rejection as it applies to claim 6 is maintained for the reasons of record. In regard to claims 4-5, 7-12, 22, this rejection is hereby withdrawn.

Allowable Subject Matter

26. Claims 2-4, 38-39 appear to be allowable over the prior art of record.
27. Claim 33 is objected to since it depends upon a rejected base claim.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

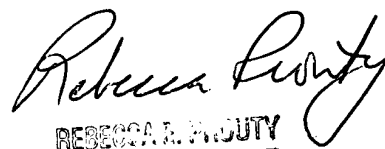
30. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
March 21, 2003


REBECCA A. PROUTY
PRIMARY EXAMINER
GROUP 1800
1600